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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,218	02/26/2002	Bryn Hird	8473M	8600
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THE PROCTER & GAMBLE COMPANY INTELLECTUAL PROPERTY DIVISION WINTON HILL TECHNICAL CENTER - BOX 161 6110 CENTER HILL AVENUE CINCINNATI, OH 45224			EXAMINER DI NOLA BARON, LILIANA	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/083,218

Applicant(s)

HIRD ET AL.

Examiner

Liliana Di Nola-Baron

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_. 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 17-22 and 27-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising an open-celled polymeric foam, does not reasonably provide enablement for the complete list of diseases, for which Applicant claims methods of treatment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The asserted utility is not believable on its face.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

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(1) The nature of the invention:

The invention is directed to methods of treating a disease or condition comprising administering a composition comprising an open-celled polymeric foam.

(2) The state of the prior art

The prior art (U.S. Patent 5,750,585 to Park et al.) teaches that polymeric foams may be orally administered to treat obesity or deliver active agents (See col. 15, lines 16-32).

(3) The relative skill of those in the art

The relative skill of those having a doctorate degree in the medical arts is high.

(4) The predictability or unpredictability of the art

The predictability or lack thereof in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results from the claimed invention. The lower the predictability, the higher the direction and guidance that must be provided by Applicant.

(5) The breadth of the claims

The method claims are very broad. No dosage of polymeric foam is recited in the claims, even though the dosage is likely to vary due to the lack of correlation between diseases.

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(6) The amount of direction or guidance presented

The amount of direction and guidance provided by Applicant is limited to the formulations comprising HIPE foam. There is no evidence in the specification that established correlation between the different diseases claimed by Applicant , nor between the experiments and the claimed utility.

(7) The presence or absence of working examples

The working examples present no data on the effect of the compositions of the invention on the treatment of the various diseases.

(8) The quantity of experimentation necessary

The effect of the compositions of the invention on the possible treatment of diseases, for which no correlation has been established, cannot be predicted a priori but must be determined from the case to case by painstaking experimental study in vivo. When the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine a possible treating effect of the compositions and methods claimed in the instant application.

***Claim Objections***

3. Claim 5 is objected to because of the following informalities: the specific surface area should be expressed in  $\text{m}^2/\text{cm}^3$ . Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by DesMarais et al. (U.S. Patent 5,260,345).

The patent discloses a foam composition having an open-celled structure, and teaches that HIPE is the preferred foam (See col. 3, lines 30-53 and col. 5, lines 25-45). Additionally, the patent teaches that the foam has a density in the range of 0.01-0.08 g/cm<sup>3</sup> (See col. 9, lines 49-54), a specific surface area in the range of 0.5-5 m<sup>2</sup>/g (See col. 8, lines 48-52) and a pore volume of 12-100 ml/g (See col. 7, lines 40-43). Finally, the patent teaches that the foam is formed from styrene monomers having a Tg above 40°C and acrylate monomers having a Tg of 40°C (See col. 17, lines 3-43).

Thus, the patent provides an open-celled polymeric foam composition as claimed in claim 1 of the instant application. The purpose of the composition claimed by Applicant in instant claim 1 has no patentable weight in a composition claim.

The density value claimed in instant claim 2 is in the range disclosed by the patent.

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With regard to claims 3 and 4, the patent teaches that the HIPE foam is formed from styrene and acrylate monomers (See col. 17, lines 3-43), as claimed by Applicant.

With respect to claim 5, the patent teaches Tg values (40°C), which are in the range claimed by Applicant (See col. 17, lines 3-43). With regard to the specific surface area per foam volume claimed by Applicant, by dividing the specific surface area by the foam volume disclosed by the patent, one obtains a specific surface area per foam volume value of 0.04-0.05 m<sup>2</sup>/ml, which is more than 0.01 m<sup>2</sup>/cc, as claimed by Applicant.

The compositions disclosed by the patent meet the limitations of claims 1-5 of the instant application, as the patent contemplates open-celled polymeric foam compositions as claimed by Applicant. Thus, the patent anticipates the claimed invention.

6. Claims 1-3, 10, 11 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Park et al. (U.S. Patent 5,750,585).

The patent provides open-celled foam compositions and a method of orally administering said foams compositions and treating obesity (See col. 3, lines 15-25 and col. 15, lines 16-32). Thus the patent discloses compositions comprising a foam having an open cell structure and methods comprising administering an open-celled polymeric foam and treating obesity, as claimed in instant claims 1, 10 and 17. The sequestering of lipophilic materials claimed by Applicant in instant claim 10 is inherent to the composition used in the method of the invention. With regard

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to claims 2 and 11, the patent teaches that the composition has a density of 0.015-07 (See col. 7, lines 35-41), thus the patent contemplates a density less than 0.1, as claimed by Applicant.

Regarding claim 3, the patent teaches that that the foams are formed from polyacrylic acid, as claimed by Applicant (See col. 4, lines 1-6).

The compositions and method disclosed by the patent meets the limitations of claims 1-3, 10, 11 and 17 of the instant application, as the patent contemplates administering an open-celled foam composition for the treatment of obesity and produce weight loss. Thus, the patent anticipates the claimed invention.

### *Claim Rejections - 35 USC § 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 6, 23 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al. (U.S. Patent 5,750,585) in view of Niazi (U.S. Patent 6,251,421).

The teachings of Park et al. have been summarized above. With regard to claims 6, 23 and 25-27, Park et al. teaches that the composition of the invention can be used as oral drug delivery system (See col. 13, line 63 to col. 15, line 20). Park et al. is deficient in the sense, that the patent does

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not specify the drugs, which can be delivered by the composition of the invention. With respect to claim 27, Park et al. does not specifically include instructions in the composition of the invention.

Niazi discloses pharmaceutical compositions comprising a lipase inhibitor, specifically orlistat (also known as tetrahydrolipstatin) having the structure claimed in instant claim 26, and teaches that the composition reduces fat absorption and can be administered in oral dosage forms for the treatment of obesity and hyperlipidemia (See col. 2, line 24 to col. 3, line 61). Additionally, Niazi teaches that the composition can be in the form of commercial pack containing a lipase inhibitor and instructions for its use in the treatment of obesity or hyperlipidemia (See col. 3, lines 39-44).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include a lipase inhibitor in the drug delivery foam compositions disclosed by Park et al. to device compositions and kits reducing fat absorption and methods for treating obesity and hyperlipidemia, as taught by Niazi. The expected result would have been successful compositions and kits for fat absorption and treatment of obesity. Because of the teachings of Park et al., that open-celled foam compositions can be used as oral drug delivery system, and the teachings of Niazi, that lipase inhibitor compositions can be administered in oral dosage forms for reducing fat absorption and treating obesity, one of ordinary skill in the art would have a reasonable expectation that the compositions and kits claimed in the instant application would be successful in reducing fat absorption and treating obesity. Therefore the

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invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

9. Claims 1, 4, 10, 12, 13, 17, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitagawa (U.S. Patent 6,218,440).

Kitagawa provides HIPE emulsions to form microbeads for use as drug microcarriers (See col. 12, lines 25-35). With regard to claims 1, 4, 10, 12, 17 and 18, Kitagawa does not specifically mention that the HIPE emulsion is a foam, however, Kitagawa teaches that a HIPE can be formed as disclosed in U.S. Patent 5,149,720 to DesMarais et al. (See col. 12, lines 32-35). In U.S. Patent 5,149,720 Des Marais et al. discloses a process for the continuous preparation of high internal phase emulsions, which are suitable for subsequent polymerization into polymeric foam materials (See Abstract). Thus, the emulsions disclosed by Kitagawa can be foams. With regard to the methods claimed in instant claims 10 and 17, Kitagawa teaches that the compositions of the invention can be used as drug carriers and the high void volume of HIPE provides exceptional absorbency (See col. 14, line 52 to col. 15, line 1). With regard to claims 13 and 19, the patent is deficient in the fact that the patent does not provide a specific amount of HIPE composition, which is administered to an animal, however, one of ordinary skill in the art would have been able to determine the optimal amount by routine experimentation and clinical trials.

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Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Kitagawa. to device compositions and methods comprising HIPE. The expected result would have been successful compositions and methods for fat absorption and treatment of obesity. Because of the teachings of Kitagawa., that HIPE compositions can be used as drug delivery system and have exceptional absorbency, one of ordinary skill in the art would have a reasonable expectation that the compositions and methods claimed in the instant application would be successful in reducing fat absorption and treating obesity. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

10. Claims 7-9, 14-16 and 20-24, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitagawa (U.S. Patent 6,218,440) in view of Niazi (U.S. Patent 6,251,421).

The teachings of Kitagawa have been summarized above. Kitagawa et al. teaches that the HIPE can be used as drug carrier, however, the patent fails to specifically disclose the drugs, which can be delivered by the HIPE compositions of the invention.

Niazi discloses pharmaceutical compositions comprising a lipase inhibitor, specifically orlistat (also known as tetrahydrolipstatin) having the structure claimed in instant claims 9, 16 and 22, and teaches that the composition reduces fat absorption and can be administered in oral dosage forms for the treatment of obesity and hyperlipidemia (See col. 2, line 24 to col. 3, line 61).

Additionally, Niazi teaches that the composition can be in the form of commercial pack

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containing a lipase inhibitor and instructions for its use in the treatment of obesity or hyperlipidemia (See col. 3, lines 39-44).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include a lipase inhibitor in the drug delivery HIPE compositions disclosed by Kitagawa to device compositions and kits reducing fat absorption and methods for treating obesity and hyperlipidemia, as taught by Niazi. The expected result would have been successful compositions, kits and methods for fat absorption and treatment of obesity. Because of the teachings of Kitagawa, that HIPE compositions can be used as drug delivery system, and the teachings of Niazi, that lipase inhibitor compositions can be administered in oral dosage forms for reducing fat absorption and treating obesity, one of ordinary skill in the art would have a reasonable expectation that the compositions and methods claimed in the instant application would be successful in reducing fat absorption and treating obesity. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. After February 4, 2004, the examiner's telephone number will be 571-272-0592. The examiner can normally be reached on Monday through Thursday, 8:30AM-7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached at 703-308-2927. After February 4, 2004, Mr.

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Thurman Page can be reached at 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

*Sen83*

January 7, 2003

**THURMAN K. PAGE**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**